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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,731	11/20/2001	David Botstein	P2730P1C70	2397

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HELLER EHRMAN WHITE & MCAULIFFE LLP  
275 MIDDLEFIELD ROAD  
MENLO PARK, CO 94025-3506

EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/989,731

Applicant(s)

ASHKENAZI ET AL.

Examiner

Fozia M Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 December 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 119-127, 129-131 and 135-145 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 119-127, 129-131 and 135-145 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/13/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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**Response to an Amendment**

1. Receipt of Applicants' arguments and amendments filed in on 25 December 2004 is acknowledged. Claims 119-127, 129-130, 135 have been amended, claims 128, 132-134 have been canceled, and new claims 139-145 have been added. Thus claims 119-127, 129-131, 135-145 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed on 12/25/04:

(I) The amendment to specification for removing embedded hyperlink, is acknowledged.

(II) The rejection of claims 119-124 and 132-138, made under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification, is withdrawn, because the amended claims describe the claimed invention both in structural and functional terms.

(III) All rejections of claims 128, 132-134 are moot because these claims have been canceled.

(IV) The rejection of claims 129-131 made under 35 U.S.C § 102(b) as being anticipated by INCYTE (INCY), (WO 00/00610, June/2000), is withdrawn, because the effective filing date of these claims is 11 February 2000, which predates the publication of the WO 00/00610 patent.

***Information Disclosure Statement:***

3a. All of the references cited on the information disclosure statements filed 13 August 2004 have been considered.

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**Priority:**

4a. Applicants contend that the claimed subject matter was disclosed in the international PCT application PCT/US00/03565, filed 11 February 2000, therefore, the present application is entitled to the filing date of 11 February 2000.

Applicants' assertion that the subject matter defined in instant claims, is disclosed in the international application PCT/US00/03565 is correct in part. The international application PCT/US00/03565 discloses that the nucleic acid of SEQ ID NO:407 is amplified in lung and colon tumors. Therefore, the claimed subject matter is afforded an effective filing date of 11 February 2000, in so far as it pertains to an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:407. Claims that are drawn to variants of the nucleic acid of SEQ ID NO:407 are afforded the effective filing of the current application which is 20 November 2001.

**Claim Rejections - 35 U.S.C. § 112:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. The rejection of claims 119-127, 135-138 made under 35 U.S.C. 112, first paragraph, is maintained for reasons of record set forth in the office action mailed on 13 May 2004, pages 3-6. These claims were not rejected under 35 U.S.C. 101 for lacking utility, however these claims were rejected under 35 U.S.C. 112, first paragraph, for not enabling all the recited limitations. Therefore, Applicants' arguments regarding utility will not be addressed.

Applicants argue that "gene expression or polypeptide expression" have no bearing on the instant claims that claim nucleic acids. Applicants point out that the instantly amended claims are directed to naturally occurring nucleic acids encoding PR01245 that are amplified in lung or colon cancer, and not to polypeptides or mRNA - products of gene expression. Applicants submit the this rejection which addresses gene/ polypeptide expression based on the teachings of Pennica et al. which discuss gene expression, is misplaced. Instead, Applicants submit that, based on the instant disclosure, which details how to make and use nucleic acid variants and the advanced knowledge in the art at the time of filing, one skilled in the art would know exactly what nucleic acid variants the instant claims encompass and would know how to make and use these nucleic acids for the diagnosis of lung or colon cancer without undue experimentation; for example, by using diagnostic methods based on hybridization to such amplified sequences. Applicants argue that they have clearly demonstrated utility for the PR01245 nucleic acid as a lung or colon tumor markers. Accordingly, Applicants request that the present 35 U.S.C. 35 101/U.S.C. 112, first paragraph, utility rejections should be withdrawn.

These arguments have been considered but are not deemed persuasive. Again the instant claims are rejected under 35 U.S.C. 112, first paragraph and not under 35 U.S.C. 101, because the instant specification is only enabling for the isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:407 (full length) and does not enable "all possible" nucleic acids encoding the polypeptide of SEQ ID NO:408 or variants of the nucleic acid of SEQ ID NO:407. The Pennica et al. reference, which

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discusses gene expression, is not misplaced, because it demonstrates that the protein levels cannot be accurately predicted from the level of the corresponding gene.

Therefore, while the instant specification discloses that the nucleic acid of SEQ ID NO:407 is amplified in lung and colon tumors, it does not disclose that all nucleic acids encoding the polypeptide of SEQ ID NO:408 or variants of the nucleic acid of SEQ ID NO:407 are also amplified.

Applicants' argument that one skilled in the art would know how to make and use the claimed invention is not found persuasive, because one skilled in the art can make and use the nucleic acid of SEQ ID NO:407 for diagnosing lung and colon tumors. However, the skilled artisan would not be able to use all the encompassed variants for diagnosing lung or colon tumors, because the specification does not establish a link between the encompassed variants and these conditions.

The instant claims are drawn to nucleic acid encoding the polypeptide of SEQ ID NO:408, however, the instant specification discloses that the nucleic acid of SEQ ID NO:407 is amplified in lung and colon tumors. Therefore, the specification does not disclose that all nucleic acids that encode the polypeptide of SEQ ID NO:408 or any variants of the nucleic acid of SEQ ID NO:407 are also amplified in these tumor tissues.

Thus, while instant specification is enabling for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:407, the specification is non enabling for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:408 or variants of the nucleic acid of SEQ ID NO:407.

***Claim rejections-35 USC § 102(b):***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6a. Claims 119-127, 135-145 are rejected under 35 U.S.C § 102(b) as being anticipated by GENENTECH INC. (GETH), (WO 99/63088, December/1999); DIADEXUS LLC. (DIAD), (WO 99/60160 November/1999).

Applicants agree that the claimed invention is entitled to at least an effective date of February 11, 2000 for this application. Accordingly, WO 99/63088, dated December/1999 and WO 99/60160, dated November/1999 are 102(a) art instead. Applicants submit that WO 99/63088, dated December/1999 is the Applicants own work and can be overcome with an affidavit if necessary. Further, Applicants submit that the nucleic acids and polypeptides of SEQ ID NO: 407 and 408 were cloned, sequenced and disclosed in U.S. provisional application 60/097978, filed 8/26/1998 as SEQ ID NOs: 2 and 1 (Figures 2 and 1) and priority has been claimed to this provisional application in this application as well. Therefore, Applicants contend that the claimed invention of PR01245 and its encoding nucleic acids predate the WO 99/60160, dated on November /1999.

Applicants' assertion that the subject matter defined in instant claims is disclosed in the international application PCT/US00/03565 is found persuasive in part. Only claims drawn to the nucleic acid of SEQ ID NO:407 are afforded an effective filing date

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of 11 February 2000, (see above 4a of this office action). Furthermore, although U.S. provisional application 60/097978, filed 8/26/1998 discloses the nucleic acid of SEQ ID NO:407 and the polypeptide of SEQ IDNO:408, it fails to disclose how to use said molecules, thus, it does not provide a specific and substantial asserted utility or a well established utility for the claimed invention, to satisfy 35 U.S.C. 112, first paragraph.

Claims 119-127, 135-145 are rejected under 35 U.S.C § 102(b) and claims 129-131 are rejected under 35 U.S.C § 102(a) as being anticipated by WO 99/63088, dated December/1999 reference. Applicants contend that this is their own work, however, the authors of this reference and the inventive entity of the current application are not the same. Therefore, this rejection is maintained for reasons of record set forth in the office action mailed on 13 May 2004, page 8.

Claims 119-127, 135-145 are rejected under 35 U.S.C § 102(b) and claims 129-131 are rejected under 35 U.S.C § 102(a) as being anticipated WO 99/60160, dated on November /1999. This reference predates the effective filing date of the rejected claims, which is 20 November 2001 (claims 119-127, 135-138) and 11 February 200 (claims 129-131, 139-145). Therefore, this rejection is maintained for reasons of record set forth in the office action mailed on 13 May 2004, page 8.

Claims 119-127, 135-138 are rejected under 35 U.S.C § 102(a) as being anticipated by WO 00/00610, published on June/2000, this reference predates the effective filing date of the rejected claims, which is 20 November 2001. Therefore, this rejection is maintained for reason of record set forth in the office action mailed on 13 May 2004, page 8.



***New Rejections necessitated by Applicant's Amendment:***

***Claim Rejections - 35 U.S.C. § 102:***

7a. New claims 139-145 are rejected under U.S.C. § 102 (b) as being anticipated by Woessner et al. (Accession Number AF086152, published on 29 August 1998).

Woessner et al disclose an isolated nucleic acid molecule that comprises at least 471 contiguous nucleotides of the nucleic acid of SEQ ID NO:407 of the instant application. (See attached copies of the comparison of SEQ ID NO:407 of the instant invention and the sequence of the references (SEQUENCE COMPARISON 'D').

Instant claims 139-145 are drawn to an isolated nucleic acid that is at least 20 to 100 nucleotides in length that hybridize to the nucleic acid of SEQ ID NO:407. Therefore, since the Woessner et al reference comprises at least 471 nucleotides of SEQ ID NO:407, it would be expected to hybridize to the complement of the nucleic acid of SEQ ID NO:407, and the complement of the Woessner et al nucleic acid would be expected to hybridize to the nucleic acid of SEQ ID NO:407. Therefore, the Woessner et al reference anticipates instant claims 139-145 in the absence of any evidence to the contrary.

***Conclusion:***

8. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information:***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
15 March 2005

  
JANET ANDERSON  
PRIMARY EXAMINER